

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

3 IN RE NEW ENGLAND

4 COMPOUNDING PHARMACY, MDL No. 2419

5 INC., PRODUCTS LIABILITY Dkt No.

6 LITIGATION 1:13-MD-2419 (RWZ)

7 THIS DOCUMENT RELATES TO:

8 All Actions

9  
10 Videotaped Deposition of William Allen Mixon, M.D.  
11 Tuesday, March 22, 2016  
12 At 10:00 a.m.

13 Taken at:  
14 Aloft Hotel  
15 210 East Trade Street  
16 Charlotte, North Carolina

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18  
19  
20  
21  
22 Reported by LeShaunda Cass-Byrd, CSR, RPR  
23  
24  
25

NEW ENGLAND COMPOUNDING PHARMACY INC. PRODUCTS LIABILITY  
VIDEOTAPED DEPOSITION OF WILLIAM ALLEN MIXON, M.D. on 03/22/2016

Pages 2..5

Page 2		Page 4	
1	APPEARANCES OF COUNSEL:	1	Violations of the Law by Pharmacies
2	On Behalf of the Plaintiff Steering Committee:	2	Compounding Bio-Identical Hormone
3	FREDRIC L. ELLIS, Esq.	3	Replacement Therapy Drugs 141
4	Ellis & Rapacki LLP	4	Exhibit 1440 Article published San Francisco
5	85 Merrimac Street	5	Chronicle, Sunday, June 23rd, 2002,
6	Suite 500	6	titled: Chronicle Investigation,
7	Boston, Massachusetts 02114	7	Who is Mixing your Drugs? Bad
8	617.523.4800	8	Medicine. Pharmacy Mix-Up, a
9	BEN GASTEL, Esq.	9	Recipe for Misery. Some
10	Branstetter Stranch & Jennings, PLLC	10	Drugstores Operate with very
11	223 Rosa L. Parks Avenue	11	Little Oversight 201
12	Suite 200	12	Exhibit 1441 ASHP Article - Students Death
13	Nashville, Tennessee 37203	13	Sparks Concerns about Compounded
14	615.254.8801	14	Preparation 227
15	On behalf of Speciality Surgery Center:	15	Exhibit 1442 ASHP, Publication Pharmacy
16	KENT E. KRAUSE, Esq.	16	News, December 11th, 2006 228
17	Brewer Krause Brooks & Chastain PLLC	17	Exhibit 1443 FDA News Release 233
18	611 Commerce Street	18	Exhibit 1444 Article published in the Journal
19	Suite 2600	19	Of American Dental Association 236
20	Nashville, Tennessee 37203	20	Exhibit 1445 Promotional pieces from The
21	615.256.8787	21	Compounding Pharmacy called Mortar
22	Kkrause@bkblaw.com	22	And Pestle 236
23	On behalf of Defendant STOPNC Tennessee Clinic:	23	Exhibit 1446 Editorial from the editor of the
24	MATTHEW H. CLINE, Esq.	24	Journal of the American Dental
25	Gideon Cooper & Essary PLC	25	Association 241
	Suite 1100		
	315 Deaderick Street		
	Nashville, Tennessee 37328		
	615.254.0400		
Page 3		Page 5	
1	DEPOSITION OF WILLIAM ALLEN MIXON	1	Exhibit 1447 Post on a blog, Migraine.com. 251
2	By Mr. Gastel 8	2	Exhibit 1448 Post on The Compounding Pharmacy's
3	By Mr. Ellis 169	3	Website on June 21, 2012 268
4	By Mr. Cline 340	4	Exhibit 1449 Post on The Compounding Pharmacy's
5	DEPOSITION EXHIBITS	5	Website, September 15th, 2012,
6	EXHIBIT DESCRIPTION PAGE	6	Titled Quality Control 281
7	Exhibit 1428 TOC for Compounder Depo Notebook 15	7	Exhibit 1450 PCAC, June 18, 2015 285
8	Exhibit 1429 Amended Deposition Notice 19	8	Exhibit 1451 ASRS Letter 291
9	Exhibit 1430 E-mail Exchange between Matt Cline,	9	Exhibit 1452 Chart compiled by the Pew
10	Ben Gastel, Rick Ellis 20	10	Charitable Trusts in November
11	Exhibit 1431 Copy of the Notes of conversation	11	Of 2015 299
12	between Mr. Mixon and Mr. Connelly 26	12	Exhibit 1453 February 24, 2015 Excerpt from
13	Exhibit 1432 Notes 28	13	Pharmacy Compounding Advisory
14	Exhibit 1433 Letter Exchanges between William	14	Committee of the FDA 324
15	Mixon from Matthew Cline 36	15	Exhibit 1454 Page from The Compounding
16	Exhibit 1434 William Mixon Report 39	16	Pharmacy's web site in September
17	Exhibit 1435 865th Meeting of the North	17	Of 2012 327
18	Carolina Board of Pharmacy	18	Exhibit 1455 The Compounding Pharmacy Adrenal
19	Exhibit 1436 Handwritten Notes 85	19	Article 328
20	Exhibit 1437 The Compounding Pharmacy is	20	Exhibit 1456 The Compounding Pharmacy Andropause
21	On Facebook 126	21	Article 329
22	Exhibit 1438 North Carolina Board of Pharmacy	22	Exhibit 1457 The Compounding Pharmacy Sterile
23	Pharmacist FAQs 134	23	Compounding Article 331
24	Exhibit 1439 Document Titled: Seeking FDA	24	Exhibit 1458 (No Exhibit 1458 marked)
25	Actions to Counter Flagrant	25	Exhibit 1459 Wall Street Journal Article 334

NEW ENGLAND COMPOUNDING PHARMACY INC. PRODUCTS LIABILITY  
VIDEOTAPED DEPOSITION OF WILLIAM ALLEN MIXON, M.D. on 03/22/2016

Pages 198..201

<p style="text-align: right;">Page 198</p> <p>1 of corticosteroids."</p> <p>2 Do you see that?</p> <p>3 A. Uh-huh (affirmative).</p> <p>4 Q. And then it says, "Our findings are in</p> <p>5 agreement with those reported by NG, et al., who were</p> <p>6 first to document the significant increase in the</p> <p>7 growth rate of <i>Aspergillus fumigatus</i> or <i>Aspergillus</i></p> <p>8 <i>flavus</i> exposed to hydrocortisone."</p> <p>9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. And it's Footnote 7. Do you see that?</p> <p>12 The -- the NG study?</p> <p>13 A. Yes. Yes.</p> <p>14 Q. Turn -- turn to Footnote 7. That was a</p> <p>15 study that was published back in a journal called</p> <p>16 <i>Microbiology</i> in 1994, correct?</p> <p>17 A. Uh-huh (affirmative). By Dr. --</p> <p>18 Q. Eng.</p> <p>19 A. -- Eng. Dr. E-n-g. That's his name.</p> <p>20 Q. Okay. So prior to today, you were not</p> <p>21 aware that steroids or MPA could actually enhance,</p> <p>22 stimulate the growth of fungi?</p> <p>23 A. No.</p> <p>24 MR. CLINE: Object to the form.</p> <p>25 BY MR. ELLIS:</p>	<p style="text-align: right;">Page 200</p> <p>1 prescription for disaster if not made right?</p> <p>2 A. I would --</p> <p>3 Q. Okay.</p> <p>4 A. -- but I disagree that we're unregulated.</p> <p>5 We're highly regulated.</p> <p>6 Q. Well, it doesn't say unregulated. It says</p> <p>7 the compounding pharmacies are a little-known, lightly</p> <p>8 regulated shadow world of the American pharmaceutical</p> <p>9 industry.</p> <p>10 I take it you disagree with that?</p> <p>11 A. I don't. That's inflammable.</p> <p>12 Q. Okay. So let's go down the sixth paragraph</p> <p>13 that talks about, "In 2001, 11 people in Northern</p> <p>14 California developed bacterial infections from</p> <p>15 injections of steroid betamethasone."</p> <p>16 That is another type of injectable steroid,</p> <p>17 correct?</p> <p>18 A. Yes.</p> <p>19 Q. "Made by a compounding pharmacy. Three</p> <p>20 died.</p> <p>21 "A year later, two people in Michigan</p> <p>22 developed bacterial meningitis from methylprednisone.</p> <p>23 Neither died.</p> <p>24 "That same year, seven people became ill</p> <p>25 and two died from fungal infections caused by</p>
<p style="text-align: right;">Page 199</p> <p>1 Q. So let's go back to the Washington Post</p> <p>2 article, the third paragraph of the article.</p> <p>3 "In short, methylprednisone acetate, an</p> <p>4 injectable steroid in pharmaceutical pilots, is a</p> <p>5 prescription for disaster if not made right. A</p> <p>6 few" --</p> <p>7 MR. KRAUSE: Where are you are?</p> <p>8 BY MR. ELLIS:</p> <p>9 Q. "A few drug companies make it. So do an</p> <p>10 unknown number of compounding pharmacies, a</p> <p>11 little-known, lightly regulated shadow world of the</p> <p>12 American pharmaceutical industry."</p> <p>13 Do you see that?</p> <p>14 A. Yes.</p> <p>15 Q. Okay.</p> <p>16 MR. KRAUSE: If that was a question,</p> <p>17 I object to the form.</p> <p>18 THE WITNESS: Is that a question?</p> <p>19 Yes, I see it.</p> <p>20 BY MR. ELLIS:</p> <p>21 Q. It was a question.</p> <p>22 A. I see what it says.</p> <p>23 Q. Okay.</p> <p>24 A. Did you ask me if I agreed with it?</p> <p>25 Q. Well, do you agree that -- that it's a</p>	<p style="text-align: right;">Page 201</p> <p>1 contaminated methylprednisone made by a compounding</p> <p>2 pharmacy in South Carolina.</p> <p>3 "Last spring, contaminated steroids</p> <p>4 injected into the eyes of patients in Florida caused</p> <p>5 13 vision-damaging infections."</p> <p>6 Do you see that?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. So let's take each one of these.</p> <p>9 Let's start with the 2001 outbreak.</p> <p>10 Now, you worked in the business of</p> <p>11 compounding in 2001, correct?</p> <p>12 A. Yes.</p> <p>13 Q. We are going to mark this as Exhibit 1440.</p> <p>14 (Plaintiff's Exhibit 1440 was marked</p> <p>15 for identification.)</p> <p>16 BY MR. ELLIS:</p> <p>17 Q. This is an article that was published in</p> <p>18 the San Francisco Chronicle, Sunday, June 23rd, 2002.</p> <p>19 And it's entitled, "Chronicle Investigation, Who is</p> <p>20 Mixing your Drugs? Bad Medicine. Pharmacy Mix-Up, a</p> <p>21 Recipe for Misery. Some Drugstores Operate with very</p> <p>22 little Oversight."</p> <p>23 Do you see that?</p> <p>24 A. Yes.</p> <p>25 Q. And the first paragraph talks about --</p>



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VIDEOTAPED DEPOSITION OF WILLIAM ALLEN MIXON, M.D. on 03/22/2016

Pages 202..205

<p style="text-align: right;">Page 202</p> <p>1 first two paragraphs talks about a man who had</p> <p>2 received a cortisone shot for his chronic back pain.</p> <p>3 Do you see that?</p> <p>4 A. Well, at the first --</p> <p>5 Q. The first two paragraphs.</p> <p>6 A. -- paragraphs?</p> <p>7 Yes. Yes.</p> <p>8 Q. And the third paragraph, "But on May 30th,</p> <p>9 2001, less than 24 hours after his cortisone shot,</p> <p>10 George Stahl was dead."</p> <p>11 A. Right.</p> <p>12 Q. The fifth paragraph, "The autopsy concluded</p> <p>13 that the seemingly healthy UPS driver was killed by</p> <p>14 meningitis."</p> <p>15 Do you see that?</p> <p>16 A. I see where it says that he died from a</p> <p>17 burst blood vessel in the brain.</p> <p>18 Q. Well, that is what the doctors first said.</p> <p>19 But then let's go to the autopsy in the next</p> <p>20 paragraph.</p> <p>21 A. "They donated his organs. The doctors were</p> <p>22 in for a shock. The organs were riddled with</p> <p>23 bacteria, and the autopsy concluded that the healthy</p> <p>24 UPS driver was killed by meningitis."</p> <p>25 Yes.</p>	<p style="text-align: right;">Page 204</p> <p>1 Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. Would you agree that that was true in 2001?</p> <p>4 MR. KRAUSE: Object to the form.</p> <p>5 THE WITNESS: Definitely the second</p> <p>6 sentence. How much oversight occurred in</p> <p>7 California at the state level, I certainly</p> <p>8 can't say.</p> <p>9 BY MR. ELLIS:</p> <p>10 Q. Well, were you aware that this resulted in</p> <p>11 legislation in California, this death and this</p> <p>12 outbreak of meningitis from an injectable steroid made</p> <p>13 by a compounding pharmacy resulted in legislation in</p> <p>14 California where they tried to impose more regulation</p> <p>15 on compounding pharmacies?</p> <p>16 A. I did not know that.</p> <p>17 MR. CLINE: Object to the form.</p> <p>18 BY MR. ELLIS:</p> <p>19 Q. Okay. That is fine.</p> <p>20 A. But do I know that California has very</p> <p>21 strict compounding regulations.</p> <p>22 Q. Okay. But you don't know when they were</p> <p>23 enacted or whether they were in enacted in response in</p> <p>24 this outbreak?</p> <p>25 A. No, I didn't know that.</p>
<p style="text-align: right;">Page 203</p> <p>1 Q. Okay. Next page. "The cortisone was later</p> <p>2 found to be contaminated with deadly bacteria. It had</p> <p>3 been made at Doc's Pharmacy in Walnut Creek."</p> <p>4 That's about a half an hour outside of</p> <p>5 San Francisco.</p> <p>6 "Where drugs were mixed from scratch in</p> <p>7 practice known as pharmacy compounding."</p> <p>8 A. Uh-huh (affirmative). Yes.</p> <p>9 Q. So back in 2001, when this happened, were</p> <p>10 you aware of this incident that occurred in -- at</p> <p>11 Doc's Pharmacy?</p> <p>12 A. I may have been. I don't recall.</p> <p>13 Q. Let me see if this refreshes your memory.</p> <p>14 The pharmacist who actually compounded it committed</p> <p>15 suicide after this. Does that ring a bell?</p> <p>16 MR. CLINE: Object to the form.</p> <p>17 THE WITNESS: It doesn't.</p> <p>18 BY MR. ELLIS:</p> <p>19 Q. Okay. If we go two more paragraphs, the</p> <p>20 paragraph beginning, "Yet there is little."</p> <p>21 "Yet there is little oversight by either</p> <p>22 federal or state regulators to ensure the drugs made</p> <p>23 by compounders are safe or effective. And patients</p> <p>24 often have no idea that the drugs they have been</p> <p>25 prescribed are compounded."</p>	<p style="text-align: right;">Page 205</p> <p>1 Q. Okay. Let's go to the -- two paragraphs</p> <p>2 down. But it is only one of many recent incidents</p> <p>3 around the country of compounding gone awry."</p> <p>4 And then it talks about an example in</p> <p>5 Kansas City where 34 cancer patients it Kansas City</p> <p>6 were given watered-down chemotherapy drugs by a</p> <p>7 compounding pharmacist, who, when he confessed, said</p> <p>8 he was trying to save money to meet pledges he had</p> <p>9 made to his church.</p> <p>10 "In the spring, Pharmacist Richard Courtney</p> <p>11 told investigators that as many as 4,200 patients may</p> <p>12 have received diluted drugs since 1992."</p> <p>13 Were you aware of that incident?</p> <p>14 A. Yes.</p> <p>15 Q. And then he -- the reporter gives another</p> <p>16 example. "Four patients were hospitalized in an</p> <p>17 Atlanta suburb. Two in a coma, after they swallowed a</p> <p>18 compounded thyroid drug that was as much as a thousand</p> <p>19 times the prescribed strength. The pharmacist, John</p> <p>20 Marzullo, surrendered his license in February."</p> <p>21 Are you aware of that incident?</p> <p>22 A. I did not know about that.</p> <p>23 Q. Next he talks about, "Doctors reported</p> <p>24 neurological damage in eight chronic pain patients</p> <p>25 after a compounder at a Baptist Memorial Healthcare</p>



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Pages 334..337

<p style="text-align: right;">Page 334</p> <p>1 (Plaintiff's Exhibit 1459 was marked 2 for identification.) 3 BY MR. ELLIS: 4 Q. It's a Wall Street Journal article. And if 5 you take a look at the first couple of paragraphs, do 6 you see -- oh, by the way, this is the Wall Street 7 Journal, February 27th, 2004. Are you familiar with 8 that newspaper? 9 A. Certainly. 10 Q. And do you see where it says Page A-1? 11 A. Yes. 12 Q. And you are familiar with that -- that 13 is -- this is the front page. 14 A. Okay. 15 Q. Okay. The title of the article is, 16 "Stirring Debate. As druggists mix customized brews, 17 FDA raises alarm. Compounders often meet special 18 needs, but industry falls in regulatory gap. Rare 19 fungus in the steroids." 20 Do you see that? 21 A. Yes. 22 Q. Okay. This is February 2004. It's before 23 the death with the Triangle Pharmacy in late 2004 and 24 2005 and all the publicity that got. This is in 25 response to a South Carolina pharmacy called Urgent</p>	<p style="text-align: right;">Page 336</p> <p>1 public health problems, including a handful of deaths 2 linked to compounded drugs. State officials in 3 Missouri say that last year they ordered a mail order 4 compounding pharmacy to recall a batch of respiratory 5 drugs that may have been contaminated with a deadly 6 bacteria. The drugs may have reached more than 19,000 7 people. 8 "In 2001, three California patients died of 9 meningitis after receiving contaminated steroid shots 10 made by a compounder." 11 That was the incident at the Walnut Creek 12 pharmacy that we talked about. 13 And then can you turn to the last 14 paragraph -- well, the last sentence of Page 2. Could 15 you read that. "Lawyers for Urgent Care, the pharmacy 16 involved in this outbreak." 17 A. I am sorry. Starting where? 18 Q. The last sentence on Page 2. 19 A. "The pharmacy has filed for Chapter 7 20 liquidation bankruptcy and is no longer operating." 21 Is that the sentence you were referring to? 22 Q. Yes. 23 And then at the top of Page 3, please, 24 first sentence? 25 A. Well, this is talking about "Urgent Care</p>
<p style="text-align: right;">Page 335</p> <p>1 Care Pharmacy. Does that strike a bell, that that was 2 the pharmacy? 3 A. Yes. 4 Q. Okay. And it talks about this man, Donald 5 Boles -- Boles, who had fell off a ladder and ruptured 6 a disc in 2002. His doctor prescribed a spinal 7 steroid injection to ease the pain. 8 Six months later, after two more shots and 9 back surgery, the pain got worse. And a rare fungus 10 normally found only in soil was growing inside the 11 tissues of his lower back, eating away at his bones. 12 Do you see that? 13 A. Yes. 14 Q. Okay. And the second sentence of the 15 second paragraph says, "Investigators from the Center 16 for Disease Control Prevention traced the mold to a 17 batch of contaminated steroid shots that had already 18 infected five people." 19 Do you see that? 20 A. Yes. 21 Q. Okay. And then let's turn to the second 22 page of this Wall Street Journal article, the third 23 full paragraph. 24 Do you see where it says, "The tainted shot 25 Mr. Boles received was one example in a string of</p>	<p style="text-align: right;">Page 337</p> <p>1 Pharmacy in Spartanburg filing for Chapter 7 2 liquidation bankruptcy and no longer operating. 3 'Incidents such as these, which regulators found out 4 about, might be the tip of the iceberg when it comes 5 to concerns with compounding drugs because there is no 6 mandatory reporting of problems,' says David Horowitz, 7 director of the Office of Compliance and FDA Center 8 for Drug Evaluation and Research. 'Compounded 9 products aren't typically tested for safety or purity 10 before dispensed to patients.' 11 Q. Okay. So this was February 2004, front 12 page article in the Wall Street Journal. 13 MR. CLINE: Object to the form. 14 BY MR. ELLIS: 15 Q. And then -- 16 MR. KRAUSE: Object to the extent 17 that all we have done is have a section of 18 this article read into the record by either 19 the attorney or the witness. 20 BY MR. ELLIS: 21 Q. So then I want to show you exhibit -- what 22 was that exhibit? 23 MR. KRAUSE: There wasn't a single 24 question. 25 THE WITNESS: 1459.</p>



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VIDEOTAPED DEPOSITION OF WILLIAM ALLEN MIXON, M.D. on 03/22/2016

Pages 338..341

<p style="text-align: right;">Page 338</p> <p>1 BY MR. ELLIS:</p> <p>2 Q. So let me show you Exhibit 1460.</p> <p>3 (Plaintiff's Exhibit 1460 was marked</p> <p>4 for identification.)</p> <p>5 BY MR. ELLIS:</p> <p>6 Q. This is from WebMD Health News, March 24th,</p> <p>7 2005. Can you read the -- this is entitled --</p> <p>8 MR. CLINE: Rick.</p> <p>9 MR. ELLIS: I am sorry.</p> <p>10 BY MR. ELLIS:</p> <p>11 Q. This is entitled, "Closer scrutiny urged</p> <p>12 for compounded drugs. Groups decry lack of standards</p> <p>13 and labelling for drugs mixed by pharmacy labs."</p> <p>14 Do you see that?</p> <p>15 A. Yes.</p> <p>16 Q. Could you read the first two paragraphs,</p> <p>17 please.</p> <p>18 MR. KRAUSE: Same objection.</p> <p>19 THE WITNESS: "March 24th, 2005, a</p> <p>20 group of medical organizations called on</p> <p>21 the FDA to crack down on pharmacies they</p> <p>22 say concoct copycats of pharmacy products</p> <p>23 without oversight from the federal</p> <p>24 government.</p> <p>25 "The groups want the agency to</p>	<p style="text-align: right;">Page 340</p> <p>1 MR. KRAUSE: Object to the form.</p> <p>2 BY MR. ELLIS:</p> <p>3 Q. And what was the IACP's position and your</p> <p>4 position on that legislation?</p> <p>5 A. We were vehemently opposed to it.</p> <p>6 Q. And did you lobby Congress to oppose that</p> <p>7 legislation?</p> <p>8 A. I did.</p> <p>9 MR. ELLIS: I have no further</p> <p>10 questions.</p> <p>11 EXAMINATION</p> <p>12 BY MR. CLINE:</p> <p>13 Q. Mr. Mixon, I just have a couple of quick</p> <p>14 questions for you.</p> <p>15 I want to take you back to our phone call</p> <p>16 with Joe Connelly --</p> <p>17 THE COURT REPORTER: I can barely</p> <p>18 hear you.</p> <p>19 BY MR. CLINE:</p> <p>20 Q. I would like to take you back to our phone</p> <p>21 call with Joe Connelly last Sunday.</p> <p>22 Do you remember that phone call?</p> <p>23 A. Yes.</p> <p>24 Q. Do you remember whether Joe Connelly told</p> <p>25 us whether the stir plates and the isolator hoods were</p>
<p style="text-align: right;">Page 339</p> <p>1 require stricter labelling on drugs mixed</p> <p>2 by pharmacy laboratories because of</p> <p>3 concerns that patients are not aware that</p> <p>4 they are not governed by FDA-manufacturing</p> <p>5 rules."</p> <p>6 BY MR. ELLIS:</p> <p>7 Q. Okay. And do you see at the bottom of the</p> <p>8 first page, there is a paragraph talking about a group</p> <p>9 called the Consumer Health Alliance For Safe</p> <p>10 Medication that had filed a petition asking the FDA to</p> <p>11 require all compounded drug products to carry labels</p> <p>12 telling consumers that they are regulated by the</p> <p>13 agency and that they have not been tested for safety,</p> <p>14 efficacy or sterility.</p> <p>15 Do you see that?</p> <p>16 MR. KRAUSE: Object to the form.</p> <p>17 THE WITNESS: Yeah.</p> <p>18 BY MR. ELLIS:</p> <p>19 Q. And this is March of 2005, correct?</p> <p>20 A. Yeah.</p> <p>21 Q. And in 2006, Senator Edward Kennedy,</p> <p>22 Massachusetts, proposed legislation that would give</p> <p>23 the FDA back the power to regulate the compounding</p> <p>24 pharmacies, correct?</p> <p>25 A. Right.</p>	<p style="text-align: right;">Page 341</p> <p>1 large or small stir plates?</p> <p>2 MR. GASTEL: Objection to the form.</p> <p>3 THE WITNESS: He said they were</p> <p>4 small.</p> <p>5 BY MR. CLINE:</p> <p>6 Q. And did he tell us anything about the stir</p> <p>7 plates on the -- out on the table?</p> <p>8 A. Well, I saw on the videos, and he also said</p> <p>9 that they were large, commercial grade stir plates.</p> <p>10 Q. You were asked -- shown several documents</p> <p>11 about PCAB.</p> <p>12 A. Yes.</p> <p>13 Q. You were asked whether PCAB was trying to,</p> <p>14 quote, get the word out to healthcare providers.</p> <p>15 Do you remember that -- that line of</p> <p>16 questioning?</p> <p>17 A. Yes.</p> <p>18 Q. Do you -- in your opinion, did PCAB</p> <p>19 succeed?</p> <p>20 MR. GASTEL: Objection to form.</p> <p>21 THE WITNESS: No, I don't -- that</p> <p>22 was -- that was not a successful campaign.</p> <p>23 BY MR. CLINE:</p> <p>24 Q. You were also asked some questions about</p> <p>25 the availability of methylprednisone acetate.</p>